EXPANDIBLE STENT

This application is a continuation of U.S. application no. 09/893,253 filed on June 27, 2001 which is a continuation of U.S. application no. 09/063,496 filed on April 20, 1998 which is a continuation-in-part of U.S. 08/687,223 filed on July 25, 1996, which claims priority from U.K. application no. 9605486.1 filed on March 15, 1996 and U.K. application no. 9515282.3 filed on July 25, 1995 the contents of which are incorporated herein by reference.

BACKGROUND OF THE INVENTION

Expandable stents are widely used to provide local reinforcement in fluid-carrying vessels within the human body. The stent is essentially a cylindrical member which may be expanded radially to dilate the vessel and to provide support for the wall of the vessel to maintain it in the dilated condition.

SUMMARY OF THE INVENTION

In order to insert the stent, it has previously been proposed to place the stent into the vessel on an expandable or balloon catheter. With the stent positioned at the appropriate location, the catheter is inflated and the stent is caused to expand radially against the wall of the vessel. Once the stent is expanded to the required diameter, the catheter is deflated and may be removed, leaving the stent in position.

The stent must of course remain expanded against the wall or the vessel and should be capable of withstanding the forces imposed by the wall of the vessel. Moreover, the stent should be able to negotiate tight turns in the arterial system during placement while minimizing damage to the arterial wall.

A number of different mechanisms have been proposed to permit the expansion of the stent, including devices which reorient the components forming the stent so that they may adopt a greater overall diameter.

In another class of stents, as typified by the stent shown in USP 4,733,665 to Palmaz, the stent is configured to be plastically deformable so that after expansion it retains the increased diameter. In the Palmaz stent, the plastic deformation is provided by means of an open-mesh

diamond structure. As the catheter is expanded, the intersecting members of the mesh deform so that the stent adopts an increased diameter.

With the arrangements shown in the Palmaz stent and similar configurations, a radial expansion of the stent is accompanied by an axial foreshortening of the stent. The degree of foreshortening is predictable but the ultimate location of the stent along the vessel is not predictable. Thus, one end of the stent may remain stationary relative to the blood vessel so that the opposite end is subjected to the maximum axial displacement or there may be progressive foreshortening from both ends with an intermediate location remaining stationary. The foreshortening of the stent leads to an unpredictable location for the stent in its expanded condition and induces relative movement in an axial direction between the vessel wall and the stent which is generally undesirable.

It is therefore an object of the present invention to provide a stent in which the above disadvantages are obviated or mitigated.

In general terms, the present invention provides a stent in which a plurality of circumferentially-spaced longitudinal struts are interconnected by multibar linkages. Adjacent links of the linkages are angularly disposed to one another such that a radial force causes relative rotation between adjacent links to permit radial enlargement of the stent. The longitudinal struts inhibit foreshortening of the stent so that the final location of the stent can be predicted.

BRIEF DESCRIPTION OF THE DRAWINGS

Embodiments of the invention will now be described by way of example only with reference to the accompanying drawings, in which

Figure 1 is a side elevation of an assembled stent;

Figure 2 is a view on the line 2-2 of Figure 1;

Figure 3 is a developed view of the stent shown in Figure 1;

Figure 4 is a view on an enlarged scale of a portion of the stent shown in Figures 1-3;

Figure 5 is a view of the portion of the stent shown in Figure 4 after radial expansion;

Figure 6 is a view similar to Figure 4 of an alternative embodiment of stent;

Figure 7 is a view of the embodiment of Figure 6 after radial expansion;

Figure 8 is a further alternative of stent shown in Figure 4;

Figure 9 is a view of the embodiment of Figure 8 after radial expansion;

Figure 10 is a comparative curve between the embodiments of stent shown in Figures 4, 6 and 8;

Figure 11 is a perspective view of a further embodiment of stent;

Figure 12 is a developed view of the embodiment of stent shown in Figure 11;

Figure 13 is an enlarged view of a portion of the stent shown in Figure •;

Figure 14 is a view similar to Figure 9 showing the stent after radial expansion;

Figure 15 is a sectional view of a stent support and catheter;

Figure 16 is a developed view, similar to Figure 12, of a further embodiment;

Figure 17 is a developed view similar to figure 16 of a still further embodiment;

Figure 18 is an enlarged view of a portion of the embodiment of figure 17; and

Figure 19 is a developed view similar to figure 17 of a yet further embodiment.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring therefore to Figure 1, a stent 10 has a generally tubular body 12 which is initially dimensioned to permit insertion into a vessel such as an artery. The body 12 includes a plurality of longitudinal struts 14 which are interconnected by multi-bar linkages 16. The linkages 16 are regularly spaced along the axial extent of the struts 14 and maintain struts 14 in circumferentially spaced relationship.

As can best be seen in Figure 4, each of the linkages 16 includes a pair of oppositely directed circumferential links 18 with axial links 20 connected to the circumferential links 18 and extending parallel to the struts 14 but spaced therefrom. The axial links 20 are connected to an L-shaped corner link 22 which has an axial leg 24 and circumferential leg 26. The legs 26 of opposed corner links 22 are interconnected by a circumferential connecting link 28 to interconnect the adjacent struts 14. The links 18,20,22 and 28 of the linkage 16 are formed by removal of material from a seamless tube of bio-compatible material so that the links are integrally connected to one another. Typically such material would be a metal such as both pure and alloyed titanium, platinum, nitinol memory metals, gold or stainless steel, and the linkage may suitably be machined through micro machining techniques. Other materials could be used that are considered suitable for implantation including plastics materials having the requisite properties.

Each of the linkages 16 is similar and the relative dimensions between the links in each linkage determine the change in diameter for a given load. In a typical example, as shown in Figure 4, taking the length of the connecting link 28 to be of unit length, then the relative dimensions of the other links as indicated by the letters on Figure 4 are as follows:

a	b	c	d	e	f	g	h	i	J	k
1	2	I	0.625	1.125	0.125	2.125	2.0	1.375	1.125	0.125

The stent 10 is typically inserted into the vessel by using a balloon catheter 60. The stent 10 is mounted on the catheter 60 shown in Figure 15. To assist in placement of the stent 10 on the catheter 60, the stent is initially located on a support 62 that has a bar-like head 64 and a tapered body 66. The stent 10 is snugly received on the body 66 which has a concave recess 68 at one end to locate the tip of catheter 60. A bore 70 extends through the body 66 to accommodate a wire if the catheter is of the type that employs such.

A protective sleeve 72 is located over the body 66 and is retained on a boss 74 on the head 64. The sleeve 72 thus protects the stent 10 from extraneous external forces with the body 66 providing support for the stent 10 in transit.

To transfer the stent to the catheter 60, the sleeve 72 is removed and the body 66 is aligned with the catheter 60. The stent may then be slid axially from the body 66 over the catheter 60 and the support and sleeve discarded. In this way, the stent is guided during transfer and the placement of the stent on the catheter facilitated.

The recess 68 assists in locating and aligning the catheter 60 during transfer and of course the wire, if present, may be fed through the bore 70.

The stent 10 is located on the body 66 such that the links 28 are closer to the boss 74 than the associated links 18. Transfer of the stent 10 to the catheter thus ensures that the stent 10 is oriented on the catheter 60 such that the connecting link 28 of the linkage 16 is in advance of the circumferential links 18 during insertion of the stent 10 into the vessel.

The catheter is inserted into the vessel in a conventional manner until it is located at the stenosis.

After placement within the vessel, the catheter is then inflated to apply a radially expanding force to the stent.

As shown in Figure 5, the application of the radial force causes the circumferential spacing of struts 14 to increase. The circumferential links 18 are carried with the struts 14 and a hinging action occurs at the connection of the axial link 20 to both the circumferential link 18 and the comer link 22 by plastic deformation of the links. Similarly, the connecting link 28 hinges at its connection to the comer link 22 to provide a hinging action between the links. The links 22 is thus bodily rotated as the struts 14 are spread.

By virtue of the relatively narrow links 20,22, the hinging at their junction to the larger links 18,22 exceeds the yield point of the material and causes a permanent deformation and increase in diameter. A pair of spaced hinge points is thus established and thus the total rotation required between the axial links 20 and circumferential link 28 is distributed between two locations.

The catheter is then deflated and removed, leaving the stent 10 in situ. It will be noted, however, that during inflation the struts 14 maintain the axial spacing between the circumferential links 18 so that the overall length of the stent remains the same with no relative axial movement between the vessel and the stent.

In tests with samples of the configuration of Figures 4 and 5, an extension from the spacing of the struts 14 was increased from an initial value of 6 units to 8.48 units upon application of loads consistent with those used in the expansion of such stents.

An alternative embodiment of linkage 16 is shown in Figures 6 and 7, in which like components will be denoted with like reference numerals with a suffix 'a' added for clarity.

In the embodiment of Figure 6, the circumferential link 18a is formed as a pair of rectangular nodes 30,32 interconnected by a narrow bar 34. The length of the axial link 20a is reduced to .5 of a unit value and a corresponding reduction in the length of the connecting link 28 to 0.5 is made. As may be seen in Figure 7, the application of the radial load causes the connection at the bar 34 to plastically deform, allowing rotation of the rectangular bar 32. The connecting link 28a is also subjected to bending load as well as plastic deformation at the connection to the links 22a.

In tests conducted with samples of the arrangements shown in Figures 6 and 7, the initial spacing of the struts 14 was increased to 8.5 units after application of a radial force consistent with that found in balloon catheters.

A further embodiment is seen in Figure 8 where again like reference numerals will be used to denote like components with a suffix 'b' added for clarity. In the embodiment of Figure 8, the connection between the connecting links 20b and the circumferential links 18b progressively tapers to the dimension F. In a similar manner, the junction between the connecting link 28b and the link 22b progressively tapers and in each case the overall length of the links 20b,28b is reduced from 1 unit value to 0.5 unit value. A tapering in the order of 45 is found to be appropriate.

The results of tests conducted on the embodiment shown in Figures 4, 6 and 8 are represented on the curve of Figure 9. This curve represents the applied radial load and the deflection obtained and it will be seen that in each embodiment there is an initial proportional increase of load and deflection followed by a much flatter curve indicating a plastic deformation. Thereafter, the load progressively increases, indicating that the orientation of the links is approaching a linear orientation. It will be seen that the embodiment of Figure 8 provides a lower load to achieve the requisite deflections. With the provision of the relatively narrow links, it is possible to control the radial force necessary to expand the stent and the location at which the bending will occur. The force necessary to achieve radial expansion must be compatible with the forces available from a balloon catheter and the reduced width of the links permits this. Moreover, the plastic deformation of the narrow links maintains control of the orientation of the wider links during expansion.

A further embodiment is shown in Figures 11-14 offering enhanced flexibility for the stent during insertion, as may be needed to negotiate tight turns in the arterial system during placement, thereby minimizing damage to the arterial wall.

In the embodiment of Figures 11-14, each of the struts 14c is segmented so as to be comprised of either a series of unitary struts 40 or a series of linking struts 42.

The unitary struts 40 alternate with linking struts 42 about the circumference of stent 10c and in the preferred embodiment an even number of each is provided so that the linking struts 42 are diametrically opposed. It is preferred that four linking struts 42 are provided and are circumferentially spaced at 90° intervals.

Each of the unitary struts 40 extend between two of the linkages 16c so as to interconnect them. The unitary struts are spaced apart from one another by a gap indicated at 44 so that each linkage 16c is connected to only one of the adjacent linkages 16c. By contrast, the linking struts 42 extend between four of the linkages 16c and are then spaced from the next of the linking struts 42 by a space indicated at 46.

The gaps 44 between the unitary struts are circumferentially aligned to provide annular bands 48 whereas spaces 46 are staggered between alternate linking struts 42. Each of the linking struts 42 has a waist 50 to provide a region of enhanced flexibility in a plane tangential to the surface of the stent 10c. The waist 50 is aligned with one of the bands 48 and so provides the connection across the band 48 between the linkages 16c.

As can be seen in Figure 11, the waists 50 are located at diametrically opposed locations in the respective bank 48 to define a pair of pivot axes X-X. By virtue of the staggered relationship between adjacent linking struts 42, the waists 50 are displaced by 90° in adjacent bands 48 so that the pivot axes X-X are disposed at 90°.

This arrangement provides flexibility about mutually perpendicular axially spaced axes allowing relative pivotal movement between sections of the stent to conform to the vessel into which it is inserted.

The linkage 16c is shown in detail in Figure 13 and includes circumferential links 18c and axial links 20c connected by a node 32c.

The circumferential link 28c is connected to axial link 20c by corner link 22c which is formed as a rectangular leg 24c.

It will be noted that the connection of each of the links 18c,20c,28c to the struts 134, nodes 32c and corner link 22c by radiused fillets 52 that reduce local stress concentrations.

In one preferred example, the relative dimensions are as follows:

a		c		e		g		i
1.20	0.75	1.40	1.40	2.00	0.90	0.25	6.9	5.30

The fillets 52 are each 0.125 and the thickness of the material between 0.0625 and 0.125.

With this configuration, the application of a radial load results in the circumferential expansion shown in Figure 14 from which it can be seen that a uniform bending of the links 18c is obtained and that the axial links 20 have assumed a circumferential orientation.

Upon circumferential expansion, the linking struts 42 inhibit foreshortening as each band 48 has two axial struts that inhibit relative axial movement between adjacent linkages 16c. At the same time the relatively flexible waists 50 disposed at 90° to one another provides the requisite flexibility for insertion of the stent 10c.

Although the embodiment of Figure 11 shows axes of rotation at 90° to one another, alternative arrangements may be used by varying the relative orientation of the waisted links. For example, by spacing the links at 60° angles, three axes of rotation are obtained at axially spaced locations.

The following relative dimensions of linkage 16 have also been found to provide satisfactory performance:

Example I:

a	b	c	d	e	f	g	h	i
10	7.5	11	17.8	38.6	12.3	3	46	74.2

Example II:

a	B	c	d	e	f	g	h	i
10.3	7.7	12.2	17.8	38.6	12.3	3	48.2	74.2

Example III:

a	b	c	d	e	f	g	h	i
10.0	7.5	11	14.3	20.4	9.2	3	46	49

In each of these examples, the units are 0.001 inches and the thickness of the material used was 0.003 inches.

In Examples I and III, the width, ie. circumferential dimension, of the struts 14 was 5 units and the axial spacing between adjacent linkages 16 was 12 units.

In Example II, the width of the struts 14 was 2.85 units and the axial spacing between adjacent linkages was 3 units.

In each case, the linkages repeated 4 times about the circumference. The diameter of the stent prior to expansion was 65 units and after expansion with a 450 rotation of the links 20c an outside diameter of 197 units was obtained with Example II and 152.3 units with Example III. The axial spacing between linkages I6 was sufficient to permit the bodily rotation of the corner links as the stent expands radially. The provision of the strut 14 inhibits foreshortening and therefore ensures that the linkages can rotate as required.

A further embodiment is shown in Figure 16 in which like components will be identified with like reference numerals with a suffix 'd' added for clarity. The embodiment of Figure 16 is similar to that shown in Figures 12 and 13. However, each of the struts 14d is segmented into a series of unitary struts 40d that extend between two adjacent linkages 16d. The struts 40d are staggered circumferentially to alternate the direction of connection between adjacent linkages. The unitary linkages 40d are thus aligned at diametrically opposed locations and thus define a pair of orthogonal axes at axially spaced locations to provide flexibility during insertion. The stent will of course be dimensioned to fit within the intended vessel arid engage the wall when extended. A typical stent for insertion in an artery will have a diameter of between 1.5 mm and 3.5 mm when inserted and may have a diameter of between 2 mm and 12 mm when expanded.

A further embodiment is shown in figures 17 and 18 in which like reference numerals identify like components with a suffix "e" added for clarity.
The embodiment of figures 17 and 18 has unitary struts 40e distributed at diametrically opposed locations as shown in figure 16.

In the embodiment of figure 17 however the struts 40e are increased in width to approximate the width of the nodes. And, as can be seen in figure 18, the provided with radiused external corners 80 and radiused fillets 82 at the intersection with links 20e and 28e. Similarly,

the nodes 32e are provided with radiused external comers 84 and radiused fillets 86 at the connection to the links 34e and 20e.

The radiused external corners inhibit interference between adjacent pairs of links 22e and nodes 3 e as the stent 10e is expanded to ensure a uniform expansion of the inflating balloon. The fillets 82, 86 assist in stress distribution to effect the proper hinging action of the links.

The relative dimensions of the links may be adjusted to suit the requirements and in particular to suit the outside diameter of the balloon. Using the same nomenclature as used in figure 13 suitable dimensions, in inches, for three stents with different internal diameters, is as follows.

i.d.	a	b	c	d	e	F	g	h
1	0.0100	0.0060	0.0135	0.0180	0.0190	0.0110	0.0030	0.0515
2	0.0100	0.0060	0.0125	0.0180	0.0195	0.0110	0.0030	0.0505
3	0.0095	0.0060	0.0115	0.0180	0.0195	0.0110	0.0030	10.0485

It will be seen that by varying the spacing between links 20e (dimension 'c') or the length of link 34 (dimension 'a') the spacing of the struts 40e and hence the circumference may be varied. Appropriate adjustment can be made to the length of link 20e (dimension 'e') to maintain an expanded diameter of 4mm. In each of the above examples, the external corners and all fillets except those at opposite ends of the links 20 have a radius of 0.002 inches. The fillets at opposite ends of links 20e have a radius of 0.0015 inches.

A further embodiment is shown in figure 19 in which like reference numerals will be used with like components with a suffix "f' added for clarity.

In the embodiment of figure 19 each of the linkages 16f is similar to that shown in figure 18. The unitary struts 40f interconnect three linkages 18f except for the initial strut 40f adjacent one end that interconnects two linkages 18f.

Circumferentially adjacent struts 40f are staggered relative to one another so as to provide an axial overlap and a gap 46f. Accordingly, diametrically opposed connections are established at spaced axial locations to facilitate flexure of the stent 10f.